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14. ABSTRACT

1. Contingency Preparedness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors: Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY RESEARCH PERFORMANCE REPORT

SUBMITTED October 15th, 2020

Office of Naval Research

And

The National Marrow Donor Program®

500 5th St N

Minneapolis, MN 55401

I. Heading

PI: Steven Devine, M.D.

National Marrow Donor Program

N00014-20-1-2705

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main goal of all activities funded through this grant is to develop, test and mature the ability of the NMDP Coordinating Center and NMDP contracted network sites network sites to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. As a result of prior efforts in this regard a solid foundation has been established. The proposed new activities will continue to enhance and expand our capabilities in each of the four focus areas. Contingency preparedness activities will continue to integrate NMDP's role with federal, state and local agencies.

An accident, a military incident, or a terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal. But the extent of individual injuries and the likelihood of recovery in many cases will not be apparent until days or weeks after the event. Casualties will be triaged by first responders, and those with major marrow injuries who will need aggressive medical support and may be ultimately candidates for hematopoietic cell transplantation (HCT) will need to be identified. While these patients are being supported, HCT donor identification activities will be initiated because it will not be initially clear which ones may ultimately require HCT. NMDP-approved transplant centers will provide a uniform and consistent clinical foundation for receiving, evaluating and caring for casualties. NMDP Coordinating Center will orchestrate the selection and testing necessary to rapidly identify the best available donor or cord blood unit for each patient utilizing its state-of-the-art communication infrastructure, sample repository, laboratory network, and human leukocyte antigen (HLA) expertise. NMDP's on-going immunobiologic and clinical research activities promote studies to advance the science and technology of HCT transplantation to improve outcome and quality of life for the patients.

Importantly, most individuals with near-lethal marrow toxic injuries will recover their own marrow function provided they receive intensive supportive care from the medical professionals that are part of the contingency response community.[1] These professionals can save the lives of persons with severe marrow suppression using the knowledge and skills practiced every day to treat patients undergoing HCT coordinated through the NMDP.

III. Approach

A. Contingency Preparedness

HCT teams are uniquely positioned to care for the casualties of marrow toxic injuries. The NMDP manages a network of centers that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers, is dedicated to radiological disaster preparedness activities and develops procedures for response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors
Disease stage at the time of transplantation is a significant predictor of survival, decreasing the time to identify the best matched donor is critical. Methods are under development to rapidly provide the best matched donor for HCT.

C. Immunogenetic Studies in Transplantation
Improving strategies to avoid and manage complications due to graft alloreactivity is essential to improve the outcomes of HCT. Research efforts are focused on strategies to maximize disease control while minimizing the toxicity related to alloreactivity in HCT.

D. Clinical Research in Transplantation

Clinical research creates a platform that facilitates multi-center collaboration and data management to address issues important for managing radiation exposure casualties. Advancing the already robust research capabilities of the NMDP network will facilitate a coordinated and effective contingency response.

IV. Updates

A. Contingency Preparedness

Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.

During this quarter RITN continued to develop the preparedness of its network of hospitals through the following activities:

- Much of the typical activity for this quarter was not accomplished due to the impact on hospital systems from the SARS CoV-2 pandemic; RITN tasks were minimized to prevent over straining hospitals during this crisis.
- This quarter one new transplant center joined RITN (Baylor University Medical Center, Dallas, TX).
- This year we continued to co-host the Radiation Track at the National Association of County and City Health Officials (NACCHO) annual Preparedness Summit. We were joined by the Department of Energy's Radiation Emergency Assistance Center and Training Site (REAC/TS) and the Advanced Hazmat Life Support organization in this venture to ensure radiation continues to be part of the education agenda.

- Initiated a collaboration for the Department of Defense through the Uniformed Services University with the American Burn Association to assist with updating combined injury (Burn and acute radiation syndrome) treatment guidelines for use in the forward operations setting.
- In collaboration with the RITN Medical Director the RITN Acute Radiation Syndrome Treatment Guidelines were updated.
- Continued collaboration with the American Burn Association to develop advanced practice guidelines for the combined care of patients by RITN and burn centers.
- Completed the creation of adult and pediatric medical orders in the Epic Electronic Medical Record system; which is scheduled to be deployed worldwide in February 2021
- Supported Gryphon Scientific's Center for Disease Control (CDC) funded project to assess United States laboratory capabilities for ionizing radiation related testing.
- Continued to develop the Hospital Radiation Morbidity Toolkit as part of the CDC grant awarded to RITN.

B. Development of Science and Technology for Rapid Identification of Matched Donors

Expand the genetic diversity of the registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies.

Supported HLA typing of 144,621 newly registered volunteer donors between October 1, 2019 and September 30, 2020.

Modeling and analysis of registry coverage for the Warfighter

Due to potential radiation emergencies that the Warfighter may encounter, it is important to model and analyze the potential to provide warfighters with cellular therapy. In this work we created synthetic HLA haplotype frequencies based on known racial/ethnic groups of warfighters from 2017 published demographics. Then we calculated the likelihood of finding a potential donor in the Be The Match Registry for known warfighter demographic distributions. To examine potential emergency scenarios, we created synthetic multilocus unphased genotypes (MUGs) from the warfighter HLA haplotype frequencies and identified gaps in likelihood of potential donors available for warfighter treatment. Results indicate that most warfighters will have suitable adult donors though there is not an optimal match for many warfighters. The highest and lowest rates for finding optimal matches are obtained for White and Black/African American warfighters, respectively.

Warfighter Study Population

We considered the population of 2,103,415 individuals in the military force reported in a 2017 demographic profile of US warfighters. There are 6 race groups of the warfighter- White, Native Hawaiian/Pacific Islander, Black/African American, Asian, American Indian/Alaska, and Hispanic. The number of

individuals of each race group is listed in Table 1. Note that there are 73,691 individuals of military force with other/unknown race, so we did not take into account these individuals in modeling and analysis. We also considered 5 age groups: 25 years or younger, 26 to 30 years, 31 to 35 years, 36 to 40 years and 41 years or older. The percentages of the warfighter population that are in these age groups are 40.3, 20.6, 15.5, 11.0, and 12.6, respectively. As the age distribution for the individual race groups in the warfighter community are unspecified, we used these percentages to generate population subsets for each age group (Table 2).

Note that there are 73,691 individuals in the military force reported as other/unknown race, so we did not take into account these individuals in the modeling and analysis. We also considered five age groups: 25 years or younger, 26 to 30 years, 31 to 35 years, 36 to 40 years and 41 years or older. The percentages of the warfighter population that are in these age groups are 40.3, 20.6, 15.5, 11.0, and 12.6, respectively. As the age distribution for the individual racial/ethnic groups in the warfighter community are unspecified, we used these percentages to generate population subsets for each age group (Table 2).

Table 1. Race of the military force

Race Group	**Population**
White	1,487,237
Native Hawaiian/Pacific Islander	19,990
Black or African American	356,870
Asian	91,943
American Indian or Alaska	21,526
Hispanic	294,003

Table 2. Age group and population distribution of the military force

Race Group	**Y25L**	**Y26-30**	**Y31-35**	**Y36-40**	**Y41G**
White	599356	306371	230522	163596	187392
Native Hawaiian/Pacific Islander	8056	4118	3098	2199	2519
Black or African American	143818	73515	55315	39256	44966
Asian	37053	18940	14251	10114	11585
American Indian or Alaska	8675	4434	3337	2368	2712
Hispanic	118483	60565	45571	32340	37044

Be The Match Registry

According to final inventory and adult donor models 2017, National Marrow Donor Program® (NMDP) /Be The Match maintains a registry of 18,267,161 adult donor registrants as of December 31, 2016. We considered HLA haplotype frequencies of 21 U.S. racial and ethnic groups to generate synthetic haplotype frequencies for the warfighter population.

HLA Match Definitions

We considered an HLA-matching model with high-resolution matching at HLA-A, HLA-B, HLA-C, and HLA-DRB1. We have 8/8 HLA matching when we have match at all these loci and we consider a single-allele mismatch at any of these loci in case of 7/8 HLA matching.

Estimating Match Rates for the Donor Race Categories

Before we estimated the match rates of the warfighter, we calculated the match rates of the 21 donor populations. Table 3 lists the detailed race groups of the 21 donor populations and the estimated match rates. Table 3 lists the Be The Match registry race groups used to create haplotype frequencies of the warfighters.

Table 3. Detailed race groups of Be The Match Registry and corresponding match rates

Race code	Detailed race/ethnic description
AAFA	African American
AFB	African
AINDI	South Asian Indian
AISC	American Indian – South or Central Am.
ALANAM	Alaska native or Aleut
AMIND	North American Indian
CARB	Caribbean black
CARHIS	Caribbean hispanic
CARIBI	Caribbean Indian

EURCAU	European Caucasian
FILII	Filipino
HAWI	Hawaiian or other Pacific Islander
JAPI	Japanese
KORI	Korean
MENAFC	Middle Eastern or N. Coast of Africa
MSWHIS	Mexican or Chicago
NCHI	Chinese
SCAHIS	Hispanic – South or Central American
SCAMB	Black – South or Central American
SCSEAI	Southeast Asian
VIET	Vietnamese

Estimating Match Rates for the Warfighter Race Categories

To estimate the match rates for the warfighter population, we mapped known warfighter race and ethnic groups back to BTM Registry race codes. Table 4 shows the combination of the donor race groups used to create the warfighter race group.

Table 4. Race groups of Be The Match Registry used to create race groups of the warfighters.

Warfighter Racial/Ethnic Group	**Be The Match Registry Race code**
White	MENAFC + NAMER (EURCAU)
Native Hawaiian/Pacific Islander	HAWI
Black or African American	AAFA + AFB + CARB + SCAMB
Asian	AINDI + FILII + JAPI + KORI + NCHI + SCSEAI + VIET
American Indian or Alaska	AISC + ALANAM + AMIND + CARIBI
Hispanic	CARHIS + MSWHIS + SCAHIS

Adult-donor Match Likelihood for 21 donor populations

Table 5 lists the 8/8 and 7/8 match rates for the 21 donor populations. The highest and lowest match rates were found for European Caucasian and African, respectively.

Table 5. Match rates of the 21 donor populations

Race code	8/8 Match (%)	7/8 Match (%)
AAFA	22	74
AFB	18	71
AINDI	37	87
AISC	52	88
ALANAM	57	89
AMIND	62	95
CARB	21	74
CARHIS	50	91
CARIBI	41	85
FILII	48	89
HAWI	37	81
JAPI	44	89
KORI	43	88
MENAFC	52	92
MSWHIS	49	90
NAMER (EURCAU)	79	99
NCHI	45	88
SCAHIS	40	85
SCAMB	40	81
SCSEAI	32	80
VIET	48	86
AAFA	22	74

Here we identified the likelihood of finding an unrelated donor on the Be The Match registry to provide an estimate for providing cellular therapy to warfighters in the event of radiation exposure. We also identified gaps in warfighter population coverage that will assist in targeted future recruitment efforts to address deficiencies. There are some limitations of this work, and we have room for improvement. To model and analyze registry coverage, we assumed 100% adult donor availability. Availability is the percentage of donors that will agree to donate if they are a match. Sometimes donors refuse or are unable to donate despite being a match, and this availability rate varies by population. In future we will regenerate match rates while taking into account the actual percentage of donor availability. Currently, we do not have actual HLA data and age-specific population distributions for the warfighter. However, we can refresh this calculation upon obtaining any new HLA frequencies and actual population distributions for warfighters. We also plan to revamp our methods to redefine and re-estimate match rates, including consideration for greater mismatches and improved population detail to revisit assumptions.

Development of science and technology for rapid communication of HLA data

A Data Standards Hackathon and symposium was held on September 16-18, 2020. The symposium involved 13 talks and was open to the public. The agenda was focused on HL7-FHIR implementation and rapid communication of HLA. These talks were attended by 52 individuals: 28 from NMDP, 5 from industry and 19 from government or academic health centers.

The hackathon was attended by 25 participants: 13 NMDP employees, 4 industry partners and 8 from government or academic health centers. The main topics of the hackathon was testing messages from industry partners and vetting a new data format for HLA antibody testing.

Use of population genetics and machine learning to automate the donor selection process

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Oral Presentations: title and speaker

- Data Transformation Initiative — Kristina Bloomquist
- Introduction to FHIR, ONC & CMS Rules — Lloyd McKenzie
- Roadmap to R5 — Lloyd McKenzie
- CIBMTR Reporting App Update — Kirt Schaper

- FHIR Implementation Guides: Tooling Lloyd McKenzie
- HL7 Genomics Reporting IG Bob Milius
- S4G Phase 3: HLA Reporting IG Bob Milius
- HML Gateway Miranda Bauer
- Converting Proprietary HLA format to FHIR Bob Milius
- HML2FHIR Update Bob Milius

C. Immunogenetic Studies in Transplantation

Evaluate HLA disparity and impact on HCT by adding selected pairs to the Donor/Recipient Pair project utilizing sample selection criteria that optimize the new data generated by the typing project.

Donor Recipient Pair Project

- The study team selected >8,600 pairs for enrollment in the project and used grant funds to support approximately half of the typing costs. All selected sample pairs have shipped to the project laboratory for testing. All results were received within the quarter and to date, >7700 pairs have been audited for use in research studies. The remainder of the pairs will be audited in the next quarter.

Full HLA Gene Matching Analysis

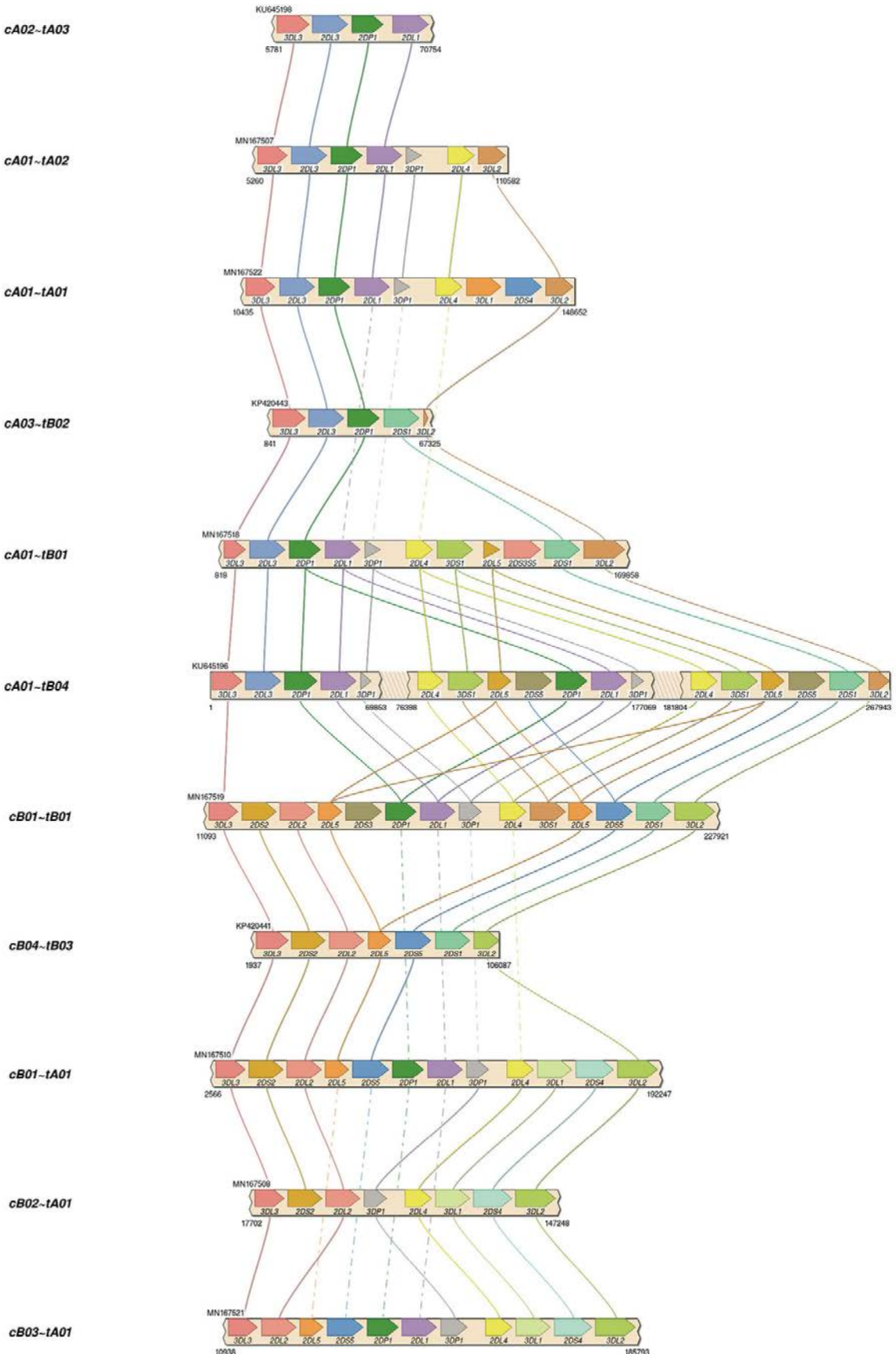
- Completed the preliminary analysis for the study IB19-01: Impact of ultra-high resolution (UHR) HLA matching on the outcome of unrelated donor hematopoietic cell transplantation. A draft manuscript is complete and is under review by the writing committee for approval for submission. Summary of findings:
    a. UHR matching was not associated with the primary outcome of overall survival in the T cell deplete, T cell replete or full cohort.
    b. 12/12 UHR matching was associated with lower aGVHD2-4 compared to <=11/12 UHR matched.
    c. TCE non-permissive mismatch was associated with worse aGVHD2-4 than matched: HR=1.26 (1.10,1.45), P=0.0007.
    d. The combination of TCE and CMV 'TCE_CMV' was associated with OS, TRM, DFS and relapse in various models (full cohort, TCD and T replete). Although highly statistically significant they are not consistent with hypothesized biologic mechanisms.
    e. The HLA-DPB1 TCE effect was weaker than previously observed in CIBMTR studies (Pidala et al Blood 2014) HR 1.2 vs. 1.08 for permissive vs. non-permissive

mismatching. A post-hoc power calculation suggests that a sample size of N=21,267 would be required to detect a difference at the 0.05 significance level with 80% power. Study team reviewing differences between the Pidala and current cohort to identify factors that could have influenced the impact of DPB1-TCE matching.

Develop and mature typing protocols for the highly polymorphic KIR.

A manuscript "Efficient Sequencing, Assembly, and Annotation of Human KIR Haplotypes" has been published in Frontiers in Immunology (https://www.frontiersin.org/articles/10.3389/fimmu.2020.582927/full). This study was supported under this grant and is a collaboration with industry partners to deliver a new typing protocol for the highly polymorphic KIR. This method addresses the limitations inherent in "shotgun" based methods by using hybrid probe capture to sequence large (2-8k) fragments of DNA on a new sequencing platform and assembling these in a way that preserves two inherited genomic segments without ambiguity. This method has been shown to provide results that are concordant with more expensive methods for Fosmid cloning and sequencing at < $1/10^{th}$ of the price. With continued support we hope to further multiplex this method to achieve another order of magnitude drop in price which will allow large research cohorts to be fully characterized at the genomic level in this highly polymorphic and structurally varying region for the first time.

The figure below, from the paper, shows the genomic arrangements observed in a set of 8 European and 8 African donors. The variation in terms of deletions and duplications of entire chromosomal segments is substantial. Investigation of the clinical impact of this structural and allele variation, especially its role in hematopoietic stem cell transplantation, has not possible at this scale until now.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MN167507
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5260
110582
cA01~tA01
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17702
147248
cB03~tA01
MN167521
3DL3 2DL2 2DL5 2DS5 2DP1 2DL1 3DP1 2DL4 3DL1 2DS4 3DL2

Determine the frequency and risks associated with donor clonal hematopoiesis of indeterminate potential in HCT.

- Completed the preliminary analysis for the study entitled "GV19-01:Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot study".
- The detected CHIP frequency was ~10% vs. the expected 15% rate used for the power calculations. Leaving the study underpowered.
- No associations were found between presence of donor CHIP and any clinical outcomes in either univariate (see table below) or multivariate analysis (data not shown).
- CHIP was called at VAF >0.02 for preliminary analysis, which aligns with prior published studies of CHIP in allogeneic transplantation. The study team has been evaluating approaches to produce accurate calls at VAF <0.02. This could increase the CHIP frequency, but with no hint of any associations at the current VAF it is unclear whether this will impact the current results.
- The lack of an association between CHIP and any clinical outcomes in the present analysis and other studies has diminished enthusiasm for further investigation of CHIP as a donor selection factor.

Table: Univariate results of GV19-01: Exploring the link between donor-engrafted clonal hematopoiesis and adverse outcomes in allogeneic hematopoietic cell transplant recipients: Pilot study

	CHIP+ (N = 30)		CHIP- (N = 269)		
Outcomes	**N**	**Prob (95% CI)**	**N**	**Prob (95% CI)**	**P Value**
Overall survival	30		269		0.882
100-day		83.3 (68.2-94.3)%		94.4 (91.4-96.8)%	
6 months		76.7 (60.2-89.8)%		85.9 (81.5-89.8)%	
1-year		76.7 (60.2-89.8)%		68.8 (63.1-74.2)%	
Disease free survival	30		267		0.898
100-day		73.3 (56.4-87.3)%		86.9 (82.6-90.7)%	
6 months		70 (52.7-84.8)%		69.7 (64-75)%	
1-year		63.3 (45.6-79.4)%		56.9 (51-62.8)%	
Relapse	30		267		0.173
100-day		13.3 (3.6-27.9)%		9.4 (6.2-13.1)%	
6 months		13.3 (3.6-27.9)%		22.1 (17.3-27.3)%	
1-year		20 (7.7-36.3)%		30 (24.6-35.6)%	
Treatment related mortality	30		267		0.165
100-day		13.3 (3.6-27.9)%		3.7 (1.8-6.4)%	
6 months		16.7 (5.6-32.2)%		8.2 (5.2-11.8)%	
1-year		16.7 (5.6-32.2)%		13.1 (9.3-17.4)%	
Chronic GVHD	30		268		0.496
100-day		0%		2.6 (1-4.9)%	
6 months		10 (1.9-23.4)%		17.2 (12.9-22)%	
1-year		NE		41 (35.2-47)%	

D. Clinical Research in Transplantation

Conduct clinical outcomes research using the CIBMTR research database and repository.

Observational Research

- Published 13 manuscripts in peer-reviewed journals during the last quarter and a total of 81 manuscripts during the grant year (Oct. 1, 2019-Sept. 30, 2020).
- CIBMTR and BMTCTN submitted 24 abstracts to the 2020 American Society of Hematology Annual Meeting. All were accepted with 9 assigned to oral presentations and 15 as poster presentations. The study titles, presentation type and presenting author are noted below.

Study Title	Presentation type	Presenting author
A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplantation to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Advanced Myelodysplastic Syndrome: Blood and Marrow Transplant Clinical Trials Network Study 1102	**Oral**	Corey Cutler
Comparison of Outcomes after Haploidentical Relative and HLA Matched Unrelated Donor Transplantation with Post-Transplant Cyclophosphamide Containing Gvhd Prophylaxis Regimens	**Oral**	Mahasweta Gooptu
Impact of Cryopreservation of Donor Grafts on Outcomes of Allogeneic Hematopoietic Cell Transplant (HCT)	**Oral**	Jack Hsu
Bridging the Gap in Access to Transplant for Underserved Minority Patients Using Mismatched Unrelated Donors and Post-Transplant Cyclophosphamide: A National Marrow Donor Program/be the Match (NMDP/BTM) Initiative	**Oral**	Bronwen Shaw
Comparison of Haploidentical Donor Hematopoietic Cell Transplantation Using Post-Transplant Cyclophosphamide to Matched-Sibling, Matched-Unrelated, Mismatched-Unrelated, and Umbilical Cord Blood Donor Transplantation in Adults with Acute Lymphoblastic Leukemia: A CIBMTR Study	**Oral**	Matthew Wieduwilt
Chromosomal Aberrations in Pre-HCT Blood Samples and Outcomes after Transplantation in Patients with Myelofibrosis	**Oral**	Youjin Wang

Expanded Comorbidity Definitions Improve Application of the Hematopoietic Cell Transplantation Comorbidity Index (HCT-CI) for Children and Young Adults with Non-Malignant Diseases Receiving Allogeneic Hematopoietic Cell Transplantation	**Oral**	Larisa Broglie
Superiority of Thiotepa-Containing Conditioning Regimens in Patients with Primary Diffuse Large B-Cell Lymphoma (DLBCL) of the Central Nervous System (CNS) Undergoing Autologous Hematopoietic Cell Transplantation (autoHCT)	**Oral**	Trent Wang
Population Distribution of GvL and GvH Minor Histocompatibility Antigens	**Oral**	Kelly Olsen
Allogeneic Hematopoietic Cell Transplantation (allo-HCT) in T-Cell Prolymphocytic Leukemia (T-PLL): An Analysis from the CIBMTR	**Poster**	Hemant Murthy
Impact of Age on the Outcomes of HCT for AML in CR1: Promising Therapy for Older Adults	**Poster**	Joseph Maakaron
Improving Donor Selection for Haploidentical Stem Cell Transplantation with Post-Transplant Cyclophosphamide through Selective HLA-Mis/Matching	**Poster**	Ephraim Fuchs
Conditioning Regimens and Outcomes after Allogeneic Hematopoietic Cell Transplant for Hyperinflammatory Inborn Errors of Immunity	**Poster**	Rebecca Marsh
Outcomes of Pediatric Patients with JMML Following Unrelated Donor Transplant: The Impact of Donor KIR Gene Content and KIR Ligand Matching	**Poster**	Hemalatha Rangarajan
Geographic Disparities of Hematopoietic Cell Transplantation in Acute Myeloid Leukemia Patients in Virginia	**Poster**	Joseph Mock
Prognostic Impact of a Modified European LeukemiaNet (ELN) Genetic Risk Stratification in Predicting Outcomes for Adults with Acute Myeloid Leukemia (AML) Undergoing Allogeneic Hematopoietic Stem Cell Transplantation (HCT). a Center for International Blood and Marrow Transplant Research (CIBMTR) Analysis for the CIBMTR Acute Leukemia Writing Committee	**Poster**	Antonio Jimenez
Expanded Comorbidity Definitions Improve Applicability of the Hematopoietic Stem Cell Transplantation-Comorbidity Index for Children, Adolescents, and Young Adults with Hematologic Malignancies Undergoing Allogeneic Stem Cell Transplantation	**Poster**	Brian Friend
Meta-Analysis of Genome-Wide Association Studies of Acute Myeloid Leukemia (AML) Patients Identifies Variants Associated with Risk of 11q23/*KMT2A*-Translocated and Core-Binding Factor (CBF) AML and Suggests a Role for Transcription Elongation in Leukemogenesis	**Poster**	Lara Sucheston-Campbell
BMT CTN 1803: Haploidentical Natural Killer Cells (K-NK002) to Prevent Post-Transplant Relapse in AML and MDS (NK-REALM)	**Poster**	Sumithira Vasu
Associations of Clinical Outcomes after Allogeneic Hematopoietic Cell Transplantation with Number of Predicted Class II Restricted mHA	**Poster**	Othmane Jadi

Pre-Transplant Clonal Mosaicism Is Associated with Increased Relapse and Lower Survival in Acute Lymphoblastic Leukemia Patients Undergoing Allogeneic Hematopoietic Cell Transplant	**Poster**	Yiwen Wang
Non-Infectious Pulmonary Toxicity after Allogeneic Hematopoietic Cell Transplantation (HCT): A Center for International Blood and Marrow Transplant Research (CIBMTR) Study	**Poster**	Sagar Patel
Maintenance Use Is More Important Than the Choice of Bortezomib-Based Triplet Induction in Newly Diagnosed Multiple Myeloma Patients Undergoing Upfront Autologous Stem Cell Transplantation	**Poster**	Surbhi Sidana
Younger HLA-Matched Unrelated Donor Allogeneic Hematopoietic Cell Transplantation (allo-HCT) for Myelodysplastic Syndromes (MDS) Is Associated with Superior Disease-Free Survival Compared to Older HLA-Identical Sibling Donors: CIBMTR Analysis	**Poster**	Guru Murthy

Research data collection and systems enhancements

During the grant year, CIBMTR has continued support for electronic data submission initiatives, production FormsNet Recipient, FormsNet Donor, and AGNIS customers, as well as Data Warehouse users.

FormsNet

Continued the quarterly releases of recipient form revisions to be current with existing treatment practices, as well as implemented revisions of forms to support the cellular therapies registry. Completed and in-process enhancements within Data Capture applications include:

- The Japanese multi-language support, allowing FormsNet system and forms to display in a language other than English, was updated in July 2020 to reflect one Cellular Therapy form revision.
- Enhancements to form capabilities to support data capture for COVID-19.
- Introduced new monthly security monitoring and incorporating fixes to security vulnerabilities within the month. Nineteen vulnerabilities were fixed in August and September with release in October 2020.
- Completed the last of the six FormsNet Forms Definition Manager (FDM) grid conversions from the Telerik to Kendo ahead of Telerik's impending retirement in September 2020, thereby improving FormsNet security.
- Updated the FDM Mapping Tool to automate major portions of the AGNIS metadata mapping to decrease manual errors and the time to map FormsNet form revisions to AGNIS.
- Completed messaging and error validation enhancements, end to end integration testing, and bug fixing for the Infections Disease Marker (IDM) Automation project which will reduce the time it takes to clear a donor by automating the reporting of IDM results and improve any error handling should these messages fail to send as expected (will be in production by 10/15/20).
- Introduced combined follow-up reporting in Formsnet3 to align follow-up data collection forms to the same timepoint when recipient has had both a hematopoietic cellular transplant and a genetically modified cellular therapy.

- Implemented a new type of data validation that uses a web service call, to ensure that a valid clinical trial study ID number is being reported.
- Made Inotuzumab Supplemental form (2541 r1 & r2) "unselectable" by the Audit Tool and completed analysis on how Audit can interface with several key fields that will no longer appear on forms (to be in production by January 2021).
- Disabled DID for Donor Forms and IDM Upload Tool to support GRID requirements and 12/15/20 deadline (Successfully developed, QA tested, regression testing is underway for 10/23 release)
- Creation and configuration of a new Enterprise Service Bus (ESB) message to communicate typing results received by CORE system for customized typing orders, so that FN3 can inform users of the status of the order and the scanned form (supports impending KeyLink retirement).
- Developed and released the following data collection forms in July 2020.

Form	Form Name	Category
2030R3	Sickle Cell Disease Pre-Infusion Data	Revised recipient form
2130R3	Sickle Cell Disease Post-Infusion Data	Revised recipient form
2543R1	Gemtuzumab Ozogamicin (Mylotarg ™) Supplemental	New study form

Electronic data submission/AGNIS

CIBMTR continued support for electronic data submission initiatives and production AGNIS customers. Effort focused on development of new AGNIS instances of CIBMTR disease specific forms, and support for CIBMTR form revision updates to existing forms. The team is in process of completing communication, educational and technical project implementations to lower AGNIS submission burden and increase the client-base including but not limited to:

- Increasing the reuse of existing AGNIS modules when supporting form revisions and other Forms Builder reports enhancements
- Investigations and pilots into the acquisition of discrete / structured data elements outside of the forms context; such as acquisition of structured laboratory data from source systems.
- Additional AGNIS reports and enhancements to the AGNIS test environments to help support external users when they are testing new AGNIS forms.

Recent AGNIS and other electronic data submission accomplishments:

- Successfully connected Children's Hospital Colorado Production environment using the CIBMTR Reporting App and began exchanging:
    - Patient demographics
    - CRID assignment
    - GVHD observations

- Five form revisions have been released in Production for AGNIS users.
- AGNIS auto-population enhancement development has been completed.
- Testing and release efforts for resolution of an AGNIS 2804r6 production issue.
- Testing related to an AGNIS 4000r6 update needed after FN3 update for clinical trials field.
- Testing and release efforts for AGNIS maintenance release updates (field name changes, floating text updates, etc.)
- Testing and release efforts for AGNIS of two donor linking issues, initiated common validations testing and AGNIS auto-population test case preparation.
- Implementation of check-digit logic for AGNIS.
- Donor linking issue from external center was developed, tested and released for AGNIS.

Integrated Data Warehouse (IDW) and Unified Data Model (UDM)

CIBMTR continued to increase the capabilities of the IDW and UDM. Accomplishments include:

Integrated Data Warehouse (IDW) – Operational Data Warehouse utilized for delivery of key data to stakeholders.

- Incorporated ongoing forms revisions into the warehouse.
- Incorporated additional metric capture capability into the CIBMTR's Data Quality Dashboard.
- Added additional checks to CIBMTR's Critical Systems Dashboard to track the status of CIBMTR systems and reports.
- Implemented new processes to support CIBMTR's International CPI Processes.
- Added additional reporting capabilities to our business intelligence suite to support CIBMTR Prospective Research team needs.
- Completed pathway to capture and store survey data from CIBMTR's ePRO system.
- Enhanced Cord Blood Data Quality Report to include additional Cellular Therapy data.
- Began first round of Transplant Center data review for the 2020 Center Volumes Data Reporting project.
- Added new reports to the Quarterly Cord Blood Quality to highlight Cellular Therapy data and capture month to month data changes.
- Business Intelligence Data Sharing- Continue expansion of business intelligence tool capabilities. Adding to the existing suite of external Business Intelligence data sharing applications including the introduction of more data, dimensions and measures, stakeholder groups, and continuing data quality initiatives. Recent accomplishments include:

  Data Operations Dashboard
  - Enhanced the DataOps dashboard to include a COVID Impacts extract which collect data from Transplant Centers on impacts to specific patient's treatment plan/infusion.

- Unified Domain Model- in process of building this single source of truth of data that will contain high quality, validated data readily available to researchers for immunobiology, outcomes, and other types of analyses
  - Completed loading and validation of multiple myeloma infectious disease data into the unified database.
  - Completed mapping of pre- and post- transplant essential data (TED).
  - Completed data architecture design for bringing patient related outcomes data (ePRO) into the unified database.
  - Delivered first production CAR T-cell data sets to our Japan partners.

- Completed design for and continued building of infrastructure required to incorporate HLA donor and recipient data into the unified database.

Support for the Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial

- BMT CTN 1702: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D) trial has accrued 559 subjects through September 2020.

Rapid mobilization and collection of stem cells for HCT will decrease time to transplant and simplify the logistics of product harvest.

- Initiated preliminary discussions to plan a prospective trial to evaluate the safety and efficacy of same day stem cell mobilization using experimental agents. A draft protocol will be developed in the next quarter.

Publications

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